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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **Confirmation No. 3564**
Sadanobu SHIRAI et al. : Attorney Docket No. 2005_0152A
Serial No. 10/524,858 : Group Art Unit 1615
Filed February 18, 2005 : Examiner Hasan Syed Ahmed
PATCHES CONTAINING TULOBUTEROL :

SUBMISSION OF ENGLISH TRANSLATION OF IPRP

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

THE COMMISSIONER IS AUTHORIZED
TO CHARGE ANY DEFICIENCY IN THE
FEE FOR THIS PAPER TO DEPOSIT
ACCOUNT NO. 23-0975.

Sir:

Applicants are submitting herewith a copy of the English translation of the International Preliminary Report on Patentability issued in connection with the PCT application on which the present U.S. application is based.

Respectfully submitted,

Sadanobu SHIRAI et al.

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April 26, 2007



From the INTERNATIONAL BUREAU U

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

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Aoyama & Partners
IMP Building
3-7, Shiromi 1-chome
Chuo-ku, Osaka-shi
Osaka 5400001
JAPON

Date of mailing (day/month/year) 04 May 2006 (04.05.2006)	
Applicant's or agent's file reference 664532	IMPORTANT NOTIFICATION
International application No. PCT/JP2004/008777	International filing date (day/month/year) 16 June 2004 (16.06.2004)
Applicant TEIKOKU SEIYAKU CO., LTD. et al	

1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Masashi Honda
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 664532	FOR FURTHER ACTION		See item 4 below
International application No. PCT/JP2004/008777	International filing date (<i>day/month/year</i>) 16 June 2004 (16.06.2004)	Priority date (<i>day/month/year</i>) 20 June 2003 (20.06.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant TEIKOKU SEIYAKU CO., LTD.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 24 April 2006 (24.04.2006)
	Authorized officer Masashi Honda Telephone No. +41 22 338 70 10

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

664532

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2004/008777

International filing date (day/month/year)

16.06.2004

Priority date (day/month/year)

20.06.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant

TEIKOKU SEIYAKU CO., LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/008777

Box No. 1

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ tablet(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or tablet(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/008777

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability:
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 - 3	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1 - 3	NO
Industrial applicability (IA)	Claims	1 - 3	YES
	Claims		NO

2. Citations and explanations:

Document 1: KIM, B. -D. et al., Proceedings - 28th International Symposium on Controlled Release of Bioactive Materials and 4th Consumer & Diversified Products Conference, 2001, Vol. 1, pages 167-168

Document 2: WO 01/28531 A1 (LTS Lohmann Therapie-Systeme AG), 26 April 2001

Document 3: JP 7-285854 A (Nitto Denko Corp.), 31 October 1995

Document 4: JP 63-10716 A (Teijin, Ltd.), 18 January 1988

Claims 1-3:

The inventions of claims 1-3 do not appear to involve an inventive step over documents 1-4 cited in the ISR.

Document 1 describes an adhesive patch containing tulobuterol and olefinic acid in an acryl adhesive (refer to table 2), differing from the invention of the present application in that document 1 does not use rubber or the like as an adhesive or specify the concentration of the ingredients.

Nevertheless, document 1 describes that a rubber-based ingredient may be selected for the adhesive, and the addition of a rubber-based adhesive, a tackifier resin, a softener, or the like to the adhesive patch containing tulobuterol as described in documents 2-4 is well known to people skilled in the art. Thus trying to add those ingredients to the invention described in document 1 could easily be achieved by a person skilled in the art.

This examination does not find that experimentally optimizing the concentrations of tulobuterol and olefinic acid with the object of obtaining the desired discharge speed requires a special technical inventive idea for a person skilled in the art, or that the specification of the present application adequately indicates the effect from specifying those concentrations.